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Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

MEIJER, INC. and MEIJER DISTRIBUTION, INC., on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

UNIMED PHARMACEUTICALS, INC.; SOLVAY PHARMACEUTICALS, INC.; WATSON PHARMACEUTICALS, INC.; PAR PHARMACEUTICALS, INC., and PADDOCK LABORATORIES, INC.,

Defendants.

EDCV09-0215 SGL (OPx)

Case No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMAND

CLASS ACTION COMPLAINT

Plaintiffs Meijer, Inc. and Meijer Distribution, Inc. (collectively, "Plaintiffs" or "Meijer"), by and through their undersigned attorneys, bring this action on behalf of themselves and all others similarly situated, against Defendants Unimed Pharmaceuticals, Inc.; Solvay Pharmaceuticals, Inc. (collectively, with Unimed Pharmaceuticals, Inc., "Unimed"); Watson Pharmaceuticals, Inc. ("Watson"); Paddock Laboratories, Inc. ("Paddock"), and Par Pharmaceuticals, Inc. ("Par") (collectively, "Defendants"). Plaintiffs make the following allegations based upon personal knowledge as to those matters relating to themselves and upon information and belief as to all other matters.

I. NATURE OF THE ACTION

1. This is a civil antitrust action seeking to recover overcharges (trebled) arising out of Defendants' unlawful delay and exclusion of generic competition from the market for Androgel (testosterone topical), a drug marketed by Unimed as a testosterone replacement therapy ("TRT") for males with a deficiency or absence of endogenous testosterone.

2. As detailed below, Defendants engineered a conspiracy to restrain trade, and a scheme to monopolize the U.S. market for Androgel and its generic equivalents (the "testosterone topical market"), by substantially delaying the onset of generic competition of testosterone topical. Among other aspects of its exclusionary scheme, Unimed entered into agreements with its prospective generic competitors Par, Paddock, and Watson (collectively the "Generic Defendants"), whereby Unimed agreed in late 2006 to pay the Generic Defendants tens (if not hundreds) of millions of dollars, as well as provide other compensation, in exchange for agreements by the Generic Defendants not to sell their generic versions of Androgel for nearly a decade, until 2015 for Watson, the first Abbreviated New Drug Application filer, and until 2016 for the remaining Generic Defendants.

3. All Defendants realized that United States Patent No. 6,503,894 (the "'894 patent"), which Unimed listed in the U.S. Food & Drug Association's "Orange Book" as covering Androgel, was weak and susceptible to attack as being invalid or unenforceable. Additionally, the Generic Defendants asserted that their formulations of testosterone topical did not infringe on the '894 patent. The Generic Defendants, however, faced the uncertainty of litigation in their attempt to avoid the '894 patent, so it was in all Defendants' interests to, as they did, reach a settlement that allowed for entry of generic testosterone topical long before the expiry of the '894 patent.

4. Generic versions of brand name drugs contain the same active ingredient, and are found by the FDA to be just as safe and effective, as their brand name counterparts. The only material difference between generics and brand name drugs is their price – generics are typically at least 30% less expensive than their brand counterparts when there is a single generic competitor; this discount typically increases to 50-80% (or more) when there are multiple generic competitors on the market. As a result, generics constitute both: (a) an opportunity for drug purchasers and consumers to obtain enormous cost savings; and (b) a serious threat to the monopoly power and profits of the manufacturer of the brand name drug facing generic competition. Indeed, AB-rated generic versions of brand name drugs typically take 80% or more of the sales of a drug molecule from the brand name product within a year of generic entry.

5. Defendants' settlements are anticompetitive because Defendants apportioned among themselves the surplus from earlier generic entry that instead would have and should have accrued to direct purchasers of Androgel.

6. The dollar value of a specific drug's market generally decreases dramatically upon generic entry because the cost of an average daily dose of the brand or generic equivalent drops due to the much lower price of the generic. For example, a drug with annual sales of $500 million prior to generic entry can see the

dollar-value of its market–even if the total number of prescriptions remains the same–drop to under $100 million following generic entry. This drop benefits drug purchasers, but also presents an opportunity and a strong financial incentive for brand and generic manufacturers to collude to maintain the much higher initial dollar-value of the market by delaying generic entry. By delaying generic entry, brand and generic manufactures are able to capture excess profits and split the much higher initial dollar value of the market instead of earning, as they would in a competitive environment, much lower profits based only on the post-generic-entry dollar value of the market. That is precisely what Defendants did here.

7. In order to maintain supra-competitive pricing, Unimed and the Generic Defendants agreed to delay generic entry until 2015 and 2016 and share in the supracompetitive profits earned unlawfully during that period of delay. Unimed's multi-million dollar payments to the Generic Defendants compensated them for agreeing to delay their market entry. Unimed itself knew that it would reap excess profits during that period of unlawful delay. Defendants' anticompetitive agreements, therefore, were in everyone's financial interest—that is, everyone's except drug purchasers'.

8. Acutely aware of these economic realities of the pharmaceutical industry, Unimed engineered a scheme whereby it would, *inter alia*: (a) make significant payments to the Generic Defendants in exchange for their agreements to refrain from selling their less expensive generic versions of Androgel until either 2015 or 2016 (*i.e.*, for nearly a decade after their 2006 agreements); and (b) disguise these "exclusion payments" as payments ostensibly for: (i) licensing and/or co-promotion of Androgel (to Watson and Par); and/or (ii) back-up manufacturing of Androgel (to Par). Defendants intentionally concealed the true purpose and nature of these exclusion payments in an attempt to shield their exclusionary agreements from antitrust scrutiny.

9. Absent the illegal agreements not to compete with the Generic

Defendants, generic competition for the sale of testosterone topical would have commenced at or near the time of the settlement agreements in early 2006 (and substantially earlier than the 2015 and 2016 dates provided for in the settlement agreements with the Generic Defendants). Because of this competition in the market for testosterone topical, Plaintiffs and other direct purchasers of testosterone topical would have been able to purchase testosterone topical at significantly lower prices than they were forced to pay because of Defendants' illegal acts to delay generic competition.

10. As a result of their illegal scheme, Defendants: (1) illegally maintained Unimed's monopoly power in the market for testosterone topical in the United States; (2) fixed, raised, maintained, and/or stabilized the price of testosterone topical at supra-competitive levels; and (3) overcharged Plaintiffs and other direct purchasers of Androgel by millions of dollars by depriving them of the results of competition from cheaper generic versions of Androgel.

11. Defendants' "exclusion payment" agreements constitute horizontal market allocation agreements, which are *per se* violations of § 1 of the Sherman Act. Defendants' conduct also constitutes a conspiracy to restrain trade, in violation of §1 of the Sherman Act.

12. Similarly, as alleged in more detail below, Defendants violated § 2 of the Sherman Act through their scheme to improperly maintain and extend Unimed's monopoly power by foreclosing or delaying competition from lower-priced generic versions of Androgel.

13. Unimed's monopoly power in the market for testosterone topical was maintained through willfully exclusionary conduct, as distinguished from growth or development as a consequence of a legally obtained valid patent, other legally obtained market exclusivity, a superior product, business acumen or historical accident.

II. JURISDICTION AND VENUE

14. This Complaint is filed, and these proceedings are instituted, under Section 4 of the Clayton Act, 15 U.S.C. § 15, to recover threefold damages and the costs of suit and reasonable attorneys' fees, for the injuries sustained by Plaintiff and members of the Class of direct purchasers of Androgel from Unimed resulting from the violation by the Defendants, as hereinafter alleged, of §§ 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15.

15. Defendants transact business within this district, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district. Venue, therefore, is appropriate within this district under 15 U.S.C. § 22, and 28 U.S.C. § 1391(b) and (c).

III. THE PARTIES

16. Plaintiffs Meijer, Inc. and Meijer Distribution, Inc. (collectively, "Meijer") are corporations organized under the laws of Michigan, with their principal places of business in Grand Rapids, Michigan. Meijer is the assignee of the claims of Frank W. Kerr Co., which purchased Androgel directly from one or more of the Defendants during the Class Period, as defined below, and was injured by the illegal conduct described herein. Frank W. Kerr Co. resold to Meijer at least some of the Androgel that it purchased from Defendants during the Class period.

17. Defendant Solvay Pharmaceuticals, Inc., is a Georgia corporation with its principal place of business in Marietta, Georgia. Solvay is the U.S. subsidiary of Solvay Pharmaceuticals. Together with its wholly owned subsidiary Defendant Unimed, Solvay develops, manufactures, and markets pharmaceuticals and related products, including Androgel, in the United States. Defendant Solvay itself negotiated and/or approved Unimed Pharmaceuticals, Inc.'s relevant anticompetitive agreements concerning Androgel, the filing and prosecution of the patent cases against Par/Paddock and Watson, and has a financial interest in

Androgel.

18. Defendant Unimed Pharmaceuticals, Inc. is a wholly owned subsidiary of Solvay Pharmaceuticals, Inc., that develops, manufactures, and markets pharmaceuticals and related products, including Androgel, in the United States. Unimed Pharmaceuticals, Inc. focuses on developing and marketing drugs in with multiple indications in the therapeutic areas of cardiology, men's health (urology and endocrinology) and certain infectious diseases.

19. Defendant Par Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business in Woodcliff Lake, New Jersey. Par principally develops, manufactures and markets generic versions of brand name drugs.

20. Defendant Paddock Laboratories, Inc. is a privately-held pharmaceutical company located in Minneapolis, Minnesota. Paddock principally develops, manufactures and markets generic versions of brand name drugs.

21. Defendant Watson Pharmaceuticals, Inc. is a Nevada corporation with its principal place of business in Corona, California. Watson principally develops, manufactures and markets generic versions of brand name drugs.

IV. CLASS ACTION ALLEGATIONS

22. Plaintiffs bring this action on behalf of itself and, under Rule 23 of the Federal Rules of Civil Procedure, as representative of a Class defined as follows:

> All persons or entities in the United States who purchased Androgel in any form directly from Unimed at any time during the period from at least January 2006, until the anticompetitive effects of Defendants' conduct cease (the "Class").

Excluded from the Class are Defendants, and their officers, directors, management, employees, subsidiaries, or affiliates, and all federal governmental entities.

23. Members of the Class are so numerous that joinder is impracticable. Plaintiffs believe the Class numbers at least in the hundreds. Further, the Class is

readily identifiable from information and records in Defendants' possession.

24. Plaintiffs' claims are typical of the claims of the members of the Class. Plaintiffs and all members of the Class were damaged by the same wrongful conduct by Defendants, *i.e.*, they paid artificially inflated prices for testosterone topical and were deprived of the benefits of competition from cheaper generic versions of Androgel as a result of Defendants' wrongful conduct.

25. Plaintiffs will fairly and adequately protect and represent the interests of the Class. Plaintiffs' interests are coincident with, and not antagonistic to, those of the Class.

26. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation in the pharmaceutical industry.

27. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

28. Questions of law and fact common to the Class include:

a. whether Defendants' agreements constitute illegal market allocation agreements;

b. whether Defendants maintained Androgel's monopoly power by delaying generic entry;

c. whether direct proof of Defendants' monopoly power is available, and if available, whether it is sufficient to prove Defendants' monopoly power without the need to also define a relevant market;

d. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;

e. whether the activities of Defendants as alleged herein have substantially affected interstate commerce; and

f. whether, and to what extent, Defendants' conduct caused antitrust injury, and if so, the appropriate measure of damages.

29. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

30. Plaintiffs know of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

V. FACTUAL ALLEGATIONS

A. The Regulatory Structure Pursuant to Which Generic Substitutes for Brand Name Drugs Are Approved

31. Under the Federal Food, Drug, and Cosmetics Act (21 U.S.C. §§ 301-392), manufacturers who create a new, pioneer drug must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

32. In 1984, Congress amended the Food, Drug and Cosmetics Act with the enactment of the Hatch-Waxman amendments, called the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman").

33. Hatch-Waxman simplified the regulatory hurdles for prospective

generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to obtain FDA approval. Instead, the FDA provides an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application ("ANDA").

34. The ANDA relies on the scientific findings of safety and effectiveness included by the brand name drug manufacturer in the original NDA. The ANDA filer must demonstrate to the FDA that the generic drug it proposes to market is bioequivalent to the brand name drug.

35. As a counter-balance to this abbreviated process for bio-equivalent generic drugs, Hatch-Waxman streamlined the process for a brand name manufacturer to enforce its patents against infringement by generic manufacturers, and provided that, under certain conditions (as detailed below), the FDA could not grant a generic manufacturer final approval to market or sell a generic version of the brand name drug for up to 30 months.

36. When the FDA approves a brand name manufacturer's NDA, the FDA publishes any compound patents which (according to the brand name manufacturer) claim the approved drug in a publication entitled the "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." 21 U.S.C. § 355(j)(7)(A)(iii). In the case of method of use patents, the FDA lists in the Orange Book any patents which (according to the brand name manufacturer) claim the approved drug for its approved method of use. In listing patents in the Orange Book, the FDA merely performs a ministerial act. The FDA does not check the facts supplied to it by the brand name manufacturer, but trusts that the manufacturer will be truthful. After the NDA is approved, the brand name manufacturer may list other new patents in the Orange Book as related to the NDA, if the brand name manufacturer similarly certifies, *inter alia*, that the new patents claim either the approved drug (for compound patents) or that the patents claim the approved drug for approved methods of use (for method-of-use patents).

37. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a brand name drug), a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand name drug has expired (a "Paragraph II certification");

iii. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

21 U.S.C. § 355(j)(2)(A)(vii).

38. If a generic manufacturer files only paragraph I, II, or III certifications, then it is able to take advantage of the expedited Hatch-Waxman approval process, and the FDA must act on the application within 180 days of receipt, unless both the FDA and the applicant agree to extend the deadline. 21 U.S.C. § 355(j)(5)(A).

39. If a generic manufacturer files a Paragraph IV certification claiming that a patent listed in the Orange Book is invalid or will not be infringed, a brand name manufacturer has an opportunity to delay the final FDA approval of the ANDA and the sale of the competing generic drug on the market. When a generic drug manufacturer files a Paragraph IV certification with its ANDA, the generic manufacturer must promptly give notice of its certification to both the NDA-holder and the owner of the patent(s) at issue. If the NDA-holder initiates a patent infringement action against the ANDA filer within 45 days of receiving the

Paragraph IV certification, then the FDA may not grant final approval to the ANDA until the earlier of either: (a) 30 months from the date the ANDA is filed; or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). Thus, by listing a patent in the Orange Book and filing a suit within 45 days of receiving a Paragraph IV certification regarding the listed patent, a brand name drug manufacturer may delay when the generic drug is finally approved by the FDA, and when generic competition to the brand name drug enters the market. During the pendency of the 30 month stay, the FDA may grant "tentative approval" to an ANDA applicant if the FDA determines that the ANDA would otherwise qualify for final approval but for the stay.

40. Because of the FDA rules alleged above, brand name manufacturers have an incentive to: (a) list patents in the Orange Book, even if such patents are not eligible for listing; and (b) then sue any generic competitor that files an ANDA with paragraph IV certifications, even if such competitor's product does not actually infringe the listed patent(s), in order to delay final FDA approval of an ANDA for up to 30 months. In addition, prior to a recent change in the Hatch-Waxman regulations, brand companies could, and did, bring multiple infringement suits (based on multiple patents listed in the Orange Book) against a single ANDA, thereby obtaining independent 30-months stays associated with each suit. This practice was curtailed by a change in FDA regulations mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which, due to repeated abuses by brand manufacturers of the type described here, limited brand manufacturers to a single stay per ANDA. *See* 21 C.F.R. §§ 314.52, 314.95, 314.107(b)(3)(i)(A).

B. Generic Versions of Brand Name Drugs are Significantly Less Expensive, and Take Significant Sales Directly From the Corresponding Brand Name Versions

41. Typically, generic versions of brand name drugs are priced significantly below the brand name versions. Because of the price differentials, and other institutional features of the pharmaceutical market, generic versions are rapidly and substantially substituted for their brand name counterparts. In every state, pharmacists are permitted (and, in most states, required) to substitute an AB-rated generic product for a brand name product unless the doctor has indicated that the prescription for the brand name product must be dispensed as written. As more generic manufacturers enter the market, prices for generic versions of a drug predictably decrease even further because of competition among the generic manufacturers, and the loss of sales volume by the brand name drug to the corresponding generic accelerates.

42. An AB rating is particularly significant to a generic manufacturer because, under the statutory regime enacted by both Congress (*i.e.*, Hatch-Waxman) and most state legislatures (which enacted Drug Product Selection, or DPS laws), pharmacists may substitute an AB-rated generic version of a drug for the brand name without seeking or obtaining permission from the prescribing doctor (unless the prescription is denominated "Dispense as Written," or DAW). Indeed, both Congress and the state legislatures have actively encouraged generic substitution because of their recognition that the economics of the pharmaceutical industry prevent generic manufacturers from simultaneously: (a) engaging in the type of heavy promotion or "detailing" typically done by brand name manufacturers; and (b) providing the enormous cost savings to purchasers and consumers generated by generic drugs.

43. Generic competition enables all members of the proposed Class to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b)

purchase the brand name drug at a reduced price. However, until a generic manufacturer enters the market, there is no bioequivalent generic drug which competes with the brand name drug, and therefore, the brand name manufacturer can continue to charge supracompetitive prices profitably without losing all or a substantial portion of its brand name sales. Consequently, brand name drug manufacturers have a strong interest to use the tactics alleged above to delay the introduction of generic competition into the market.

C. Androgel and Its Generic Challengers

44. Androgel is a brand name drug marketed by Unimed and indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone. Androgel is indicated to treat those with primary hypogonadism and hypogonadotropic hypogonadism.

45. Androgel is a gel formulation of testosterone that allows for topical application and controlled release of testosterone into the bloodstream. Androgel's generic name is testosterone topical.

46. The FDA approved Unimed's NDA No. 021015 for Androgel in 2000, and Unimed began selling Androgel shortly thereafter.

47. Unimed listed the '894 patent in the FDA's Orange Book, asserting that the patent was valid and its claims covered the formulation of Androgel.

48. In early 2003, Watson filed with the FDA ANDA No. 76-737, for approval of Watson's generic equivalent to Androgel. Watson's ANDA contained a Paragraph IV certification that the '894 patent was invalid, unenforceable, and/or not infringed by its ANDA. Watson notified Unimed on July 8, 2003 that Watson had filed an ANDA containing a Paragraph IV certification that the '894 patent was invalid, unenforceable, and/or not infringed by Watson' ANDA.

49. In or about January 2006, Defendant Watson received final approval from the FDA to market its generic version of testosterone topical, and was awarded 180 days of marketing exclusivity for being the first to file an ANDA

containing a Paragraph IV certification.

50. In early 2003, Defendant Paddock filed with the FDA ANDA No. 76-744, for approval of Paddock's generic equivalent to Androgel. Paddock's ANDA contained a Paragraph IV certification that the '894 patent was invalid, unenforceable, and/or not infringed by its ANDA. Paddock notified Unimed that Paddock had filed an ANDA containing a Paragraph IV certification that the '894 patent was invalid, unenforceable, and/or not infringed by Paddock's ANDA.

51. In July 2003, Defendants Paddock and Par entered into a licensing agreement whereby Par would sell in the United States the generic version of Androgel that Paddock would manufacture.

52. Defendant Paddock's ANDA was tentatively approved on October 27, 2004.

53. In September 2006, Defendant Par announced that it purchased all rights to Defendant Paddock's ANDA for generic Androgel.

D. Defendants' Wrongful Scheme to Delay Generic Competition

54. Following Watson's 2003 ANDA filing and Paragraph IV certification, in August 2003, Unimed sued Watson for infringement of the '894 patent. No dispositive motions were filed in the underlying '894 patent litigation until late 2005.

55. Following Paddock's 2003 ANDA filing and Paragraph IV certification, in August 2003, Unimed sued Paddock for infringement of the '894 patent.

56. Unimed knew that Hatch-Waxman's automatic 30-month stay would protect Androgel from facing generic competition until early 2006, and had little incentive to settle before then.

57. Defendants reached their anticompetitive agreements in 2006, following the expiry of the 30-month stay and the FDA's final approval of Watson's ANDA, and before any dispositive motions in the underlying '894 patent

case were ruled upon.

58. Unimed agreed to pay Paddock and Par $60 million for Paddock and Par's agreement to delay market entry of their AB-rated generic version of Androgel.

59. Unimed also agreed to pay Watson for its agreement to delay market entry. Watson's 180-day exclusivity period meant that Watson effectively could block later generic entrants by delaying its own market entry. Therefore, Watson was in a more advantageous position than Par, and the amount of Unimed's payment to Watson—which amount has not been disclosed, unlike the fact of the payment which Watson *has* acknowledged—likely exceeded the $60 million that Unimed paid to Par.

60. In total, Unimed likely paid well over $100 million to the Generic Defendants to compensate them for agreeing to delay their market entry of testosterone topical.

61. Perhaps mindful that exclusion payments like those described above are *per se* illegal, Defendants touted the payments in their agreements as fees for, *inter alia*, co-promotion and back-up manufacturing. These offered rationales were pretextual, and meant to obscure the fact that Defendants agreed to horizontally allocate the market for testosterone topical and that the payments were essential Defendants' mechanism for transferring from Unimed to the Generic Defendants some of the supracompetitive profits that would be earned by Unimed during the period of delay. The co-promotion, back-up manufacturing, and other pretextual rationales for the payments were of little or no real value to Unimed, and in any event were worth far less than the tens or hundreds of millions of dollars Unimed paid to the Generic Defendants pursuant to the agreements.

62. The anticompetitive agreements between the Defendants were neither examined in-depth nor approved by any governmental antitrust authority. Indeed, since news of Defendants' anticompetitive agreements has become public, the

Federal Trade Commission (and potentially other government entities) has been pursing an investigation of Defendants' anticompetitive conduct concerning Androgel. *See FTC v. Tarriff*, No. 08-217 (RLC), 2008 U.S. Dist. LEXIS 42739, at *2 (D.D.C. June 2, 2008) (noting the FTC's investigation "to determine whether agreements between [Unimed] and Par or Paddock, or any other agreement, unlawfully delayed entry of a lower-cost generic version of the drug AndroGel").

63. Had Defendants not reached the anticompetitive agreements they would have reached a procompetitive agreement—given both sides' demonstrated interest in settling the patent litigation and avoiding ultimate adjudication of the patent issues—that would have provided immediate availability of AB-rated generic versions of Androgel.

E. Effect on Interstate Commerce

64. At all material times, Androgel, sold by Defendant Unimed, was shipped across state lines and sold to customers located outside its state of manufacture.

65. During the relevant time period, in connection with the purchase and sale of Androgel, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

66. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Defendants, as charged in this Complaint, were within the flow of, and have substantially affected, interstate commerce.

F. Monopoly Power

67. Through the anticompetitive conduct alleged herein, Unimed was able to profitably charge supracompetitive prices for testosterone topical without losing substantial sales, and thus, by definition, maintained monopoly power with respect

to testosterone topical sold in the United States. To the extent that Plaintiffs are required legally to prove monopoly power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant product market is Androgel, and AB-rated bioequivalent versions of Androgel. There are no reasonable economic substitutes for Androgel other than AB-rated bioequivalent versions of Androgel. For the entire period relevant to this case, Unimed has been able to profitably maintain the price of Androgel well above competitive levels without losing substantial sales.

68. The relevant geographic market is the United States and its territories.

69. Unimed's market share in the relevant market is and was 100% at all times relevant to this complaint.

70. Defendants' actions are part of, and in furtherance of, the illegal restraint of trade and monopolization alleged herein, were authorized, ordered or done by Defendants' officers, agents, employees or representatives while actively engaged in the management of Defendants' affairs.

71. Defendants' illegal acts to prevent the introduction and/or dissemination into the U.S. marketplace of any AB-rated generic versions of Androgel resulted in Plaintiffs and the Class paying more than they would have paid for Androgel absent Defendants' illegal conduct.

G. Effects on Competition and Damages to Plaintiff and Class

72. Defendants' exclusionary conduct has delayed or prevented the sale of AB-rated generics to Androgel in the United States, and unlawfully enabled Defendants to sell Androgel at artificially inflated prices. But for Defendants' illegal conduct, generic competitors would have been able to successfully market AB-rated generic versions of Androgel substantially before 2015, and additional generic competitors would have entered the market thereafter.

73. If manufacturers of generic testosterone topical had entered the marketplace and effectively competed with Defendants earlier, as set forth above,

Plaintiffs and other members of the Class would have substituted lower-priced generic testosterone topical for the higher-priced brand name Androgel for some or all of their testosterone topical requirements, and/or would have received a lower price (and/or discounts) on some or all of their remaining Androgel purchases.

74. During the relevant period, Plaintiffs and other members of the Class purchased substantial amounts of Androgel directly from Defendants. As a result of Defendants' illegal conduct alleged herein, Plaintiffs and other members of the Class were compelled to pay, and did pay, artificially inflated prices for their testosterone topical requirements. Plaintiffs and the other Class members paid prices for testosterone topical that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Class members were deprived of the opportunity to purchase lower-priced generic testosterone topical instead of the more expensive brand name Androgel; (2) Class members paid artificially inflated prices for generic testosterone topical and/or (3) the price of branded Androgel was artificially inflated by Defendants' illegal conduct. As a consequence, Plaintiffs and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges.

COUNT I

Restraint of Trade In Violation of Section 1 of the Sherman Act And Conspiracy to Restrain Trade, Against All Defendants

75. Plaintiffs repeat and incorporate by reference the allegations of ¶¶ 1-74 above.

76. Beginning on or about 2006, Unimed and each of the Generic Defendants engaged in continuing illegal contracts, combinations and conspiracies in restraint of trade, the purpose and effect of which was to: (a) allocate all sales of

testosterone topical in the United States to Unimed; (b) prevent the sale of generic version of testosterone topical in the United States, thereby protecting Androgel from any generic competition; and (c) fix the price at which direct purchasers would pay for Androgel at the higher, branded price.

77. By entering into these unlawful conspiracies, Defendants have unlawfully conspired in restraint of trade and committed a violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. Defendants' agreements are horizontal market allocation and price-fixing agreements between actual or potential competitors, and thus are *per se* violations of Section 1. In the alternative, Defendants' agreements are unreasonable restraints of trade in violation of Section 1, when viewed under a "quick look" or "rule of reason" mode of analysis.

78. Plaintiffs and the members of the Class have been injured in their business and property by reason of Defendants' unlawful contract, combination and conspiracy. Plaintiffs and the Class members have paid more on their purchases of Androgel than they would have paid absent Defendants' illegal conduct, and/or were prevented from substituting a cheaper generic for their purchases of the more expensive Androgel.

79. As a result of Defendants illegal conduct, Plaintiffs and the Class paid more than they would have paid for testosterone topical, absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun marketing generic versions of Androgel likely in 2006, and in any event well before 2015.

80. If manufacturers of generic testosterone topical entered the market and competed with Unimed in a full and timely fashion, Plaintiffs and other Class members would have substituted lower-priced generic testosterone topical for the higher-priced brand name Androgel for some or all of their testosterone topical requirements, and/or would have received lower prices on some or all of their remaining Androgel purchases.

81. During the relevant period, Plaintiffs and the other Class members purchased substantial amounts of Androgel directly from Unimed. As a result of Defendants' illegal conduct alleged herein, Plaintiffs and the other Class members were compelled to pay, and did pay, artificially inflated prices for their testosterone topical requirements. Plaintiffs and all of the other Class members paid prices for testosterone topical that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) class members were deprived of the opportunity to purchase lower-priced generic testosterone topical instead of expensive brand name Androgel; (2) class members were forced to pay artificially inflated prices for generic testosterone topical and/or (3) the price of branded Androgel was artificially inflated by Defendants' illegal conduct.

COUNT II

Monopolization in Violation of Section 2 of the Sherman Act Against Unimed

82. Plaintiffs repeat, and incorporate by reference, the allegations above in ¶¶ 1-74 above.

83. Unimed used various willful and exclusionary means as part of a scheme described herein to improperly maintain and extend their monopoly power in the testosterone topical market, as detailed above.

84. The goal, purpose and/or effect of Unimed's scheme was to prevent, delay, and/or minimize the success of the entry of generic testosterone topical competitors which would have sold generic testosterone topical in the United States at prices significantly below Unimed's prices for Androgel, which would have effectively caused the average market price of testosterone topical to decline dramatically.

85. The goal, purpose and/or effect of Unimed's scheme was also to maintain and extend Unimed's monopoly power with respect to testosterone topical. Unimed's illegal scheme to prevent, delay, and/or minimize the success of

the introduction into the United States marketplace of any generic version of Androgel enabled Unimed to continue charging supra-competitive prices for testosterone topical without a substantial loss of sales.

86. As a result of Unimed's illegal conduct, Plaintiffs and the Class paid more than they would have paid for testosterone topical, absent Unimed's illegal conduct. But for Unimed's illegal conduct, competitors would have begun marketing generic versions of Androgel well before they actually did, and/or would have been able to market such versions more successfully.

87. If manufacturers of generic testosterone topical entered the market and competed with Unimed in a full and timely fashion, Plaintiff and other Class members would have substituted lower-priced generic testosterone topical for the higher-priced brand name Androgel for some or all of their testosterone topical requirements, and/or would have received lower prices on some or all of their remaining Androgel purchases.

88. During the relevant period, Plaintiffs and the other Class members purchased substantial amounts of Androgel directly from Unimed. As a result of Defendants' illegal conduct alleged herein, Plaintiffs and the other Class members were compelled to pay, and did pay, artificially inflated prices for their testosterone topical requirements. Plaintiffs and all of the other Class members paid prices for testosterone topical that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) class members were deprived of the opportunity to purchase lower-priced generic testosterone topical instead of expensive brand name Androgel; (2) class members were forced to pay artificially inflated prices for generic testosterone topical and/or (3) the price of branded Androgel was artificially inflated by Defendants' illegal conduct.

89. Unimed's scheme was in the aggregate an act of monopolization undertaken with the specific intent to monopolize the market for testosterone topical in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C.

§ 2.

COUNT III

Conspiracy to Monopolize In Violation of Section 2 of the Sherman Act Against All Defendants

90. Plaintiffs repeat, and incorporate by reference, the allegations in ¶¶ 1-74 above.

91. As detailed above, the Generic Defendants conspired with Unimed to monopolize the market for testosterone topical by, *inter alia*, agreeing to keep their generic versions off the market for nearly a decade in exchange for substantial cash payments.

92. During the relevant period, Plaintiffs and the other Class members purchased substantial amounts of Androgel directly from Unimed. As a result of Defendants' illegal conduct alleged herein, Plaintiffs and the other Class members were compelled to pay, and did pay, artificially inflated prices for their testosterone topical requirements. Plaintiffs and all of the other Class members paid prices for testosterone topical that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) class members were deprived of the opportunity to purchase lower-priced generic testosterone topical instead of expensive brand name Androgel; (2) class members were forced to pay artificially inflated prices for generic testosterone topical; and/or (3) the price of branded Androgel was artificially inflated by Defendants' illegal conduct.

VI. DEMAND FOR JURY

93. Plaintiffs demand trial by jury on all issues so triable.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and the Class, respectfully pray that:

(i) The Court determine that this action may be maintained as a class action pursuant to Rule 23 of the Federal Rules of Civil

Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2) of the Federal Rules of Procedure, be given to the Class;

(ii) The acts alleged herein be adjudged and decreed to be an unlawful restraints of trade in violation of Section 1 of the Sherman Act; and willful acts of monopolization in violation of Section 2 of the Sherman Act;

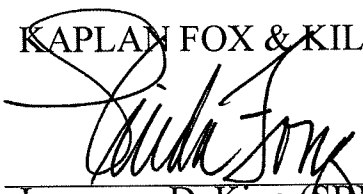
(iii) Each member of the Class recover three-fold the damages determined to have been sustained by each of them, and that joint and several judgment be entered against Defendant in favor of the Class;

(iv) The Class recover their costs of suit, including reasonable attorneys' fees as provided by law; and

(v) The Class be granted such other, further and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

Dated: February 2, 2009

KAPLAN FOX & KILSHEIMER LLP

By: 

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